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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B

A2

(11) International Publication Number: WO 98/29026

(43) International Publication Date: 9 July 1998 (09.07.98)

(21) International Application Number: PCT/US97/23913

(22) International Filing Date: 23 December 1997 (23.12.97)

(30) Priority Data:
08/775,464 30 December 1996 (30.12.96) US

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: EXPANDABLE ACCESS DEVICE AND METHOD OF CONSTRUCTING AND USING SAME

(57) Abstract

A radially expandable access device having an introducer with a plurality of leaves surrounded by a lubricous, pleated membrane is disclosed. The pressed and pleated membrane holds the leaves in an initially tight configuration to form a lumen for the insertion of a medical instrument, such as a verres needle. Because of the narrow cross-sectional profile, the size of the entry wound or other entry point necessary to gain entrance into the patient's body is very small, thereby minimizing pain and discomfort to the patient. If desired, the entry wound can later be expanded, rather than cut or torn, by the introduction of a larger instrument in the lumen of the introducer. Upon deployment of a larger medical instrument in the lumen, the leaves separate from one another as the instrument is inserted therethrough and the membrane unpleats.

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EXPANDABLE ACCESS DEVICE AND METHOD OF CONSTRUCTING AND USING SAME

Field of the Invention

The present invention relates generally to surgical access devices for use in endoscopic surgery, such devices comprising introducers, endoscopic sheaths, catheters, endoscopes, cannulas, and the like, and, more particularly, to a surgical access device having a multiple of tapered leaves forming a central lumen capable of expanding upon insertion of a medical instrument therethrough.

Background of the Invention

The advantages of minimally invasive surgery are well known and understood. For example, minimally invasive surgery reduces the trauma and pain to the patient, accelerates recovery, and shortens the average hospital stay, thus minimizing the costs of health care in the U.S. and around the world. Through the use of advanced endoscopy and other vision systems, surgery can be performed percutaneously through one or more small incisions or portals formed in the patient's body or through a bodily orifice, such as vagina, cervix, urethra, rectum, mouth, etc., or into the vascular or venous systems for use with other catheters, guidewires, and other instruments. Entrance to the body is accomplished in a number of ways depending upon the type of procedure. Once a portal or "port" is formed in the patient's body, a number of surgical access devices may be placed therethrough in order to perform the procedure. Such devices will typically include some form of endoscope or other vision system to allow the surgeon to visualize the procedure. Other surgical access devices, such as an introducer, an endoscopic sheath, catheters, or other cannulas, may be used in combination with an endoscope. The endoscopes and other endoscopic surgical instruments may be inserted through these surgical access devices. Such surgical access devices may be reusable and, thus, require sterilization (such as most endoscopes), or may be disposable (such as introducers, endoscopic sheaths, etc.). Additional procedures can be performed using other means of visualization, including fluoroscopy, ultrasonography, etc.

In addition to minimal invasiveness, there is also a trend to attempt to perform unanticipated procedures during the initial surgery so as to avoid scheduling repetitive surgeries or having to repeat entry into the surgical site with larger portals, thereby increasing surgical time or requiring further invasiveness. For example, frequently a diagnostic procedure is scheduled for a given purpose. However, once inside the patient, the surgeon might notice a cyst, polyp, lesion, or other suspicious pathology. Therefore, the surgeon may desire to perform a biopsy or other surgical procedure. If an additional diagnostic or therapeutic procedure is accomplished concurrently with the initial procedure, substantial savings in patient comfort, recovery time, and costs may be realized. Moreover, if an introducer can accommodate multiple sizes of instruments, cost savings may be realized.

Surgical access devices in the prior art require introduction of a separate dilator or sheath for expanding the initial wound site to accommodate a larger medical instrument. As a result, the access device must first be expanded by a separate expander before the larger instrument can be introduced into the access device. Moreover, because the dilating sheath is a predetermined size, the wound is often expanded more than is necessary to accommodate the instrument for that particular procedure.

Summary of the Invention

The present invention recognizes and addresses the need for an expandable surgical access device that can be expanded in a radial or generally radial direction directly by a medical instrument itself without necessarily requiring another dilator or sheath to perform the expanding function. The profile of the access device of the present invention is initially very small and is expanded only so far as is necessary to accommodate the instrument. The expansion can be radial so as to produce a larger cross-sectional circular area or the expansion can be such that other non-circular cross-sectional areas are produced. Advantageously, because dilation is achieved by the instrument itself, the incision site is not unnecessarily expanded, and thus unnecessary pain or discomfort to the patient is reduced or eliminated. In addition, the additional time and steps for expanding the initial puncture site is minimized.

Advantageously, the access device of the present invention can accommodate instruments of various sizes. Because an access device can be expanded to various sizes depending on the size of the instrument, the access device can be used in connection with a variety of medical instruments and procedures, thereby reducing the costs of supplying introducers of different sizes.

The surgical access device of the present invention can be inserted into a patient's body with only a very small initial entry incision. To facilitate entry, a verres needle or other puncture implement may be placed through the central lumen of the access device. The profile of the access device can later be expanded by removing the verres needle and introducing a larger instrument into the central lumen to expand the lumen, thereby expanding the incision as well. Thus, a separate port or second lumen is not required to accommodate the larger instrument.

By expanding or dilating the incision, the tissue is stretched as opposed to cut or torn by larger trocars and pointed insertion implements. In a preferred embodiment, the central lumen of the present access device may be expanded from 2mm to 4mm, to 8mm, or to 10mm. It is noted, however, that the lumen of the access device may be of any initially small profile, and may be expandable to any larger profile. For vascular access, once entry into the vessel is made, guidewire or additional catheter exchanges could be performed without removing the access device.

An access device made in accordance with the present invention comprises a segmented or perforated elongate member having a central lumen for receiving a medical instrument, and is surrounded by a thin, lubricous material or membrane. The segmented member comprises at least two segments and is of sufficient structural integrity to guide the instrument through the lumen to the desired location. In a preferred embodiment, the segmented elongate member comprises a plurality of leaves in close proximity to each other. The segments of the member may also be formed in other ways, such as by a single piece of material with prefabricated longitudinal slits or perforations, which can be split open upon dilation. Where the sides of the leaves or segments meet or are near each other, the leaves in combination with the membrane form an articulating joint. Thus, the leaves can move in relation to each other, particularly during expansion of the central lumen, while still maintaining a relationship to one another.

In a preferred embodiment, each leaf is identical. Each leaf is of a small thickness so that the width or diameter of the central lumen is maximized while the profile of the elongate member is initially small. In a preferred embodiment, each leaf or segment has one or more ribs or notches extending longitudinally to further aid in guiding the instrument through the lumen. While each leaf alone may be weak, the combination of leaves forms a member of sufficient rigidity and structural integrity to be inserted into a patient. Thus, the leaves provide structural support for the access device. In a preferred embodiment, each leaf is slightly rounded so that in a pre-dilated configuration, when the leaves are placed near to each other, the leaves form a rigid or semi-rigid segmented member.

The segmented elongate member has a proximal section attached to a handle, a middle section, and a distal section. In the initial pre-dilated configuration, and the distal section has a smaller profile than the profile of the proximal section. In a preferred embodiment, the segmented member comprises a cylindrical proximal section, a frusto-conical middle section whose profile decreases from that of the proximal section to that of the distal section, and an elongate cylindrical distal section. Initially, the segments are in a tight configuration such that the proximal, middle and distal sections of each segment is in close proximity to the respective proximal, middle and distal sections of its adjacent segment or leaf.

The segmented member is surrounded by a thin, lubricous material or membrane. Advantageously, the membrane does not significantly increase the profile of the introducer. As used herein, "profile" will mean a cross-sectional profile unless otherwise specified. The size of the membrane surrounding the segmented member must be sufficient to accommodate the segmented member upon expansion. While in a preferred embodiment, the membrane is basically noncompliant, in an alternate embodiment, the membrane may be elastic. The membrane closely conforms to the outer surface of the segmented member. Due to the size difference between the profiles of the proximal, middle and distal sections of the segmented member, in the preferred embodiment, the membrane is folded or pleated longitudinally along the outer surface of the segmented member.

Advantageously, the membrane can be formed or set in position on the member by the use of heat-forming or heat-shrinking techniques, or other mechanical or chemical (e.g. adhesives) means. An additional advantage of the membrane is its lubricity. As formed on the access device the material is lubricous or otherwise less-adhesive, thereby facilitating insertion of the access device into the patient and reducing discomfort to the patient. In the access device of the present invention, the membrane does not occlude the central lumen, thereby maximizing the working space within the lumen.

One advantage of the access device of the present invention is that it is self-adjusting. Because the central lumen is expanded directly by the insertion of a larger instrument therethrough, the lumen is dilated only so far as is necessary to admit the passage of the instrument being advanced through it. The central lumen holds the instrument securely along its path as it is advanced to the distal end of the access device. Advantageously, instruments of various cross-sectional profiles can be introduced through the lumen without first having to expand the lumen to accommodate that particular instrument.

In a preferred embodiment, expansion of the access device is limited to a maximum size such that the expanded device maintains enough rigidity to guide the instrument through the lumen. Further, the expansion of the

lumen may be limited by the amount of stored material surrounding the segmented member or the degree of elasticity of the membrane.

Just prior to withdrawal of the instrument, the central lumen and membrane may be easily collapsed so as to minimize any pain or trauma to the patient. By removing the instrument from the central lumen, the membrane yields to the pressure exerted by surrounding tissue, thereby reducing the outer profile of the access device to facilitate withdrawal of the access device. In addition, with the application of a slight vacuum, the unfolded membrane will conform closely to the outer surface configuration of the surgical access device for easy withdrawal.

In accordance with the method of construction of the surgical access device of the present invention, the access device can be constructed from inexpensive materials and in accordance with simple construction techniques. Advantageously, since each leaf can be identical, the leaves of the segmented member may be inexpensively manufactured, for example, by metal stamping or injection molding. Metal stamping is advantageous because the leaves may be made very thin. Moreover, notches or other features may be stamped or molded into the leaf, which can aid in the assembly, adhesive application or insert molding. For instance, grooves may be stamped into the leaf to aid in the reduction of surface contact of the instrument against the leaf. This in combination with lubricous coatings may reduce friction of the instrument as it passes through the access device.

Advantageously, due to the settable nature of the membrane material, the membrane can be folded, pleated or stored with respect to the access device on an exterior surface and can be coupled to the access device by a wide variety of means, including mechanical, adhesive, heat formation, etc. The selection of a thin polymer membrane and stamped metal or injection molded plastic as materials for the access device provides the access device with a thin streamline profile, thereby reducing the amount of force needed to enter the patient's body. In addition, these materials are advantageously inexpensive to fabricate. Thus, the access device of the present invention may be affordably supplied sterile and disposed after use, thus avoiding problems associated with re-sterilization.

While the expandable access device of the present invention can be used in a wide variety of procedures, the introducer is ideally suited for specific procedures, such as tubal sterilization and directed biopsy procedures. In an initial, unexpanded condition, the segmented member and surrounding membrane have a very small profile. Preferably in conjunction with a piercing implement or used in conjunction with guiding implements of the type used with vascular access or other applications involving bodily entry, the access device can be placed through the wall of a bodily cavity.

Once placed through the skin, placement within the peritoneal cavity or other desired location may be observed and confirmed, such as with a small profile endoscope. Grasping the handle of the introducer, the physician can then remove the verres needle or small profile instrument from the central lumen and place a larger instrument through the central lumen. More force is required to place the larger instrument through the central lumen initially as the expander dilates the tissue. Clearly, because of the versatility of the surgical access device of the present invention, a number of methods of use are available.

The expandable surgical access device of the present invention comprises an elongate member having a lumen for the insertion of a medical instrument wherein the member is formed by a plurality of longitudinal components initially positioned adjacent to one another to form the lumen and separable to provide expansion of the lumen and a membrane interconnecting the components. The expandable surgical access device of the present invention may also comprise an elongate member having a lumen for the insertion of a medical instrument and a plurality of divisible leaves initially positioned adjacent to one another to form the lumen to provide expansion of the lumen and a flexible joint formed between any two adjacent leaves. The present invention further comprises an access device having a segmented elongate member providing a lumen for the insertion of a medical instrument and having a proximal section and a distal section, wherein the distal section has a smaller profile than the profile of the proximal section and a membrane surrounding the segmented elongate member.

Brief Description of the Drawings

FIGURE 1 is a perspective view of the surgical access device of the present invention with a verres needle shown in phantom inserted therethrough.

FIGURE 2 is a side view of the surgical access device of FIGURE 1.

FIGURE 3A is a cross-sectional view of one embodiment of an access device, taken along line 3-3 of FIGURE 2, illustrating the distal end of the segmented elongate member of the access device in its initial state, prior to deployment of an expanding medical instrument through the central lumen, and further illustrating the membrane pleated and stored on the outer surface of the segmented member of the access device.

FIGURE 3B is a cross-sectional view of another embodiment of an access device, taken along line 3-3 of FIGURE 2, illustrating the distal end of the segmented elongate member of the access device in its initial state, prior to deployment of an expanding medical instrument through the central lumen, and further illustrating an alternate configuration for pleating and storing the membrane on the outer surface of the segmented member.

FIGURE 3C is a cross-sectional view of still another embodiment of an access device, taken along line 3-3 of FIGURE 2, illustrating the distal end of the segmented elongate member of the access device in its initial state, with the segments connected to each other, prior to expansion of the central lumen, and further illustrating the membrane stored on the outer surface of the segmented member.

FIGURE 4A is a cross-sectional view of the access device, taken along line 4-4 of FIGURE 2, illustrating the proximal end of the segmented elongate member of the access device in its initial state, prior to the deployment of an expanding medical instrument through the central lumen, and further illustrating the membrane surrounding the segmented member.

FIGURE 5A is a perspective view of one leaf of the access device of the present invention.

FIGURE 5B is a top plan view of the leaf shown in FIGURE 5A, with two ribs extending longitudinally along the leaf.

FIGURE 5C is a bottom plan view of the leaf shown in FIGURE 5A.

FIGURE 5D is a side view of the leaf shown in FIGURE 5A illustrating the tapered angle α of the middle section of the leaf.

FIGURE 5E is a side view of another embodiment of one leaf of the access device of the present invention illustrating the tapered angles θ, α, and β of the proximal, middle, and distal sections of the leaf, respectively.

FIGURE 6 is a side view of the access device of the present invention in an expanded state as a larger profile medical instrument, shown in phantom, is advanced therethrough.

FIGURE 7A is a cross-sectional view of the expanded access device, taken along line 7-7 of FIGURE 6, illustrating the distal end of the segmented elongate member of the access device in its expanded state, subsequent to the deployment of a medical instrument through the central lumen.

FIGURE 7B is a cross-sectional view of another embodiment of the access device, taken along line 7-7 of FIGURE 6, illustrating the distal end of the segmented elongate member of the access device in its expanded state, subsequent to the deployment of a medical instrument through the central lumen, and further illustrating two longitudinal ribs generally along the sides each leaf.

FIGURE 7C is a cross-sectional view of still another embodiment of the access device, taken along line 7-7 of FIGURE 6, illustrating the distal end of the segmented elongate member of the access device in its expanded state, subsequent to the deployment of a medical instrument through the central lumen, and further illustrating one longitudinal rib along the middle of each leaf.

Detailed Description of the Preferred Embodiment

FIGURES 1 and 2 illustrate a surgical access device or introducer 30 made in accordance with the present invention comprising a handle 32, a segmented elongate member 36 having a central lumen, and a membrane 46 (not apparent in FIGURES 1 and 2, but illustrated in FIGURES 3 and 4) surrounding the segmented member 36. In this case, a surgical introducer has been selected to illustrate the principles of the present invention; however, it will be understood that such principles apply equally to all types of surgical access devices, as well as to devices not necessarily limited to surgical access. In the broadest sense, the principles of the present invention encompass devices where an expandable lumen, is desirable or necessary in order to allow passage of some type of instrument. Such devices include, without limitation, introducers, endoscopic sheaths, catheters, cannulas, and the like. Thus, the fact that the present invention is described with respect to an introducer is illustrative only and is not intended to be limiting in any respect.

It will be understood that the present invention is compatible with all types of medical instruments, including catheters, obturators, etc. Also, visualization devices used with the present access device are not to be limited to endoscopes, but also include all types of such devices, including fluoroscopes, etc. The terms "instrument" and "endoscope" are intended to be only illustrative and representative of the wide variety of devices that can be utilized in accordance with the present method of use, and such terms are not intended to be limiting in any respect.

Referring to FIGURES 1 and 2, in a preferred embodiment of the present invention, the segmented member 36 comprises a plurality of segments, sections or leaves 38, 40 positioned in close proximity, or even connected, to one another, and connected to the handle 32. The membrane 46 in combination with the sections of the segmented member 36 form articulating joints 39, 41, 43, 45. Thus, even upon expansion of the lumen, the leaves 38, 40 cooperate to maintain the structural integrity of the access device.

The segmented member 36 has a proximal section 48 attached to the handle 32, an angled middle section 50, and a distal section 52. The length of each section may vary. In one embodiment of an access device for use in laparoscopy procedures, the proximal section 48 is about one-half inch (1.27cm) long, the middle section 50 is about one inch long (2.54cm), and the distal section 52 is about four inches (10.16cm) long. In its initial or pre-dilated configuration, the proximal section 48 and the distal section 52 of the segmented member are preferably cylindrical or generally cylindrical, with the distal section 52 having a smaller profile than the profile of the proximal section 48. Further, the middle section 50 of the segmented member is preferably frusto-conical with its profile decreasing from that of the proximal section to that of the distal section. In other embodiments, the profile of the segmented member may be, but is not limited to, continuously tapered, reverse-tapered, or generally cylindrical.

In a preferred embodiment of the present device 30, the distal tip 53 of the segmented member 36 has a tapered profile. The tapered distal profile facilitates the insertion process of the device into the patient. Furthermore, the distal edge is rounded or blunt to avoid damage to the patient's tissue upon insertion.

The handle 32 of the access device 30 is connected to the proximal section 48 of the segmented member 36. Within the handle, there may be a washer septum and duckbill valve (not shown) for maintaining an airtight system whether or not instruments are present within the system. A side port may also be provided for insufflation of media to allow for distension. It will be understood that other types of valving and conduit mechanisms can be utilized in connection with the present access device, either with or without the handle.

The Membrane

FIGURES 3A-C and FIGURES 4A-B illustrate cross-sectional views of various embodiments of the distal and proximal ends, respectively, of the segmented member in a pre-dilated configuration. As illustrated in FIGURES 3A-C and 4A-B, the membrane 46 surrounds the leaves or segments 38, 40, 42, 44 comprising the segmented member 36. The membrane 46 should be in close proximity to, and preferably in contact with, the outer surface of the segmented member 36.

In a preferred embodiment, the membrane 46 is preferably made of a thin, strong, and lubricous material. In addition, the membrane 46 should preferably be basically noncompliant both longitudinally and radially. Moreover, the membrane 46 should be malleable. That is, it should yield to the pressures and forces exerted upon it by ambient conditions, including anatomy, tissue, and other media. For instance, upon withdrawal of the larger instrument from the central lumen, the membrane may conform to its pre-dilated or at least a reduced configuration due to the pressure exerted upon it by surrounding tissue. This feature advantageously tends to reduce resistance to movement of the access device 30 and enhances patient comfort.

The size of the membrane must be sufficient to accommodate the segmented member 36 upon expansion of the lumen 58. As illustrated in FIGURES 3A and 3B, excess membrane 46 is stored to accommodate the expansion of the segmented member. Since the profile of the proximal section 48 of the segmented member 36 is larger than the profiles of the middle 50 or distal sections 52, there is excess membrane material surrounding these sections. In a preferred embodiment, this excess material is folded, pleated, or otherwise stored with respect to the outer surface of the segmented member 36 in any one of a variety of ways so as to minimize the profile of the

surgical access device 30. The excess membrane material is typically folded or doubled back on itself so as to closely conform to the outer surface configuration of the segmented member 36. FIGURES 3A and 3B illustrate two of the many ways to pleat and store the membrane 46. For example, the lateral edges of the pleats 54 can be provided with thin creases or seams 56 which can be formed and set in the membrane material. It will be understood that the present membrane 46 can be formed, wrapped, pleated or folded in a number of configurations, other than those shown in FIGURES 3A and 3B. Further, as illustrated in FIGURE 3C, the membrane 46 may be sufficiently elastic to accommodate the expansion of the central lumen, thereby eliminated the need to fold or pleat the membrane 46. Advantageously, the narrow profile of the introducer 30 is maintained.

As further illustrated in FIGURE 3C and discussed in detail below, in the pre-dilated configuration, the leaves 38, 40, 42, 44 of the segmented member may be in frictional contact or adhered, glued bonded or otherwise attached to one another.

In a preferred embodiment, the amount of the membrane 46 stored along the outer surface of the segmented member generally defines the maximum expansion of the lumen. That is, the lumen can be expanded more if there is a greater amount of stored membrane. In addition, the number and size of the leaves also affect the maximum amount of expansion so that the structural integrity of the segmented member is maintained upon expansion.

Referring to FIGURE 4, it is not necessary to fold or pleat the portion of the membrane 46 surrounding the proximal section of the segmented member because the profile of the proximal section is greater than the profile of the distal section. However, there may be excess membrane material surrounding the distal section of the segmented member depending on the desired radial expansion of the introducer, and thus, such excess material would be folded or pleated as well.

An intermediate amount of heat, such as approximately 160°F, may be applied to the membrane material so as to heat form or set it in position closely conforming to the segmented member 36. Other mechanical forming or adhesive techniques may also be employed. The settable nature of the membrane is such that a crease or seam 56 formed in the pleated material will retain a sharp, narrow profile, thus facilitating entry and use and avoiding damage or distortion to the segmented member 36.

In vivo data has demonstrated that the amount of force required to insert the device of the present invention is less than the average insertion force associated with other access devices used in laparoscopic procedures. This reduction in insertion force is facilitated by the lubricity of the membrane and the overall narrow or streamline profile of the access device of the present invention. For instance, a radially expanding introducer composed of an inner elastic material surrounded by a second braided material with an additional outermost peel-away material is commercially available. Dilation of this introducer is accomplished by placing a rigid expanding sleeve and a blunt obturator through the introducer. Once through the introducer, the blunt obturator is removed leaving the central lumen of the expanding sleeve for the placement of instruments. All of these materials in combination add to the profile of the access device and creates resistance upon entry into the body. The additional force required to insert such an introducer may create a hazard for the patient and cause unnecessary trauma or

pain to the patient. The reduction in the number of components and the thinness of each component in the introducer of the present invention reduces the overall profile of the device, thereby reducing the amount of force required to insert the device into the patient.

An in vivo porcine experiment was performed in which force gauges were placed on the proximal portions of various commercially available introducers used in laparoscopic surgery, including the introducer described above, and introducers made in accordance with the present invention. In each case a verres-needle type puncture implement was used in connection with the introducer. The results of this experiment indicate that the average insertion force of the commercially available introducers was about 7 pounds, while the average insertion force of the introducer of the present invention is about half that amount, or reduced by about 50%. Therefore, the insertion force necessary to insert the access device of the present invention in laparoscopy procedures is advantageously reduced from the force required for insertion of other expandable introducers.

In a similar experiment, force gauges were placed on instruments or expanding sleeves to measure the forces required to dilate the introducer beyond its initial entry size. The results of this experiment indicate that an average force of about 22 pounds is required to dilate the commercially available expanding introducer described above 5 mm, while the average force required to dilate the introducer of the present invention 5 mm is about 8 pounds. Thus, the amount of force necessary to dilate the access device of the present invention 5 mm is advantageously reduced.

The membrane should be thin, generally ranging in thickness between .0005 inch (0.013mm) and .002 inch (0.051mm), preferably being about .001 inch (0.025mm). Thus, even when doubled back on itself and lying on the outer surface of the segmented member 36, the membrane 46 adds only a negligible thickness to the profile of the introducer 30. In addition, because of the close conformity of the membrane 46 upon the member 36, it is less likely to be distorted or disturbed upon insertion of the introducer 30 into the body. Thus, the segmented member 36 and membrane 46 maintain structural integrity to avoid patient discomfort during insertion of the access device 30.

A number of materials can achieve these advantages of the membrane 46 of the present invention. For example, inelastic polymers or other pleated, woven, or braided materials can be utilized. Preferably, however, highly orientated or cross-linked, noncompliant polymers can be utilized as a membrane material. Such materials tend to be thermoplastically settable, with glass transitions temperatures greater than room temperature. In addition, such polymers are semicrystalline and deformable in the crystalline state. Thus, it may be folded, pleated, rolled, or otherwise stored in combination with the introducer without the loss of its advantageous mechanical properties, such as strength, noncompliance, etc. In achieving this storage position, the membrane can readily conform to the surface or space in which it is placed.

Because the membrane is thermoplastically settable, once it is stored in this position, the application of thermal energy will result in the realignment of the crystalline structure so that the membrane retains its storage position; however, it will be understood that this set in the membrane storage position can also be achieved by the application of mechanical energy or chemicals (e.g., adhesives). Thus, it can be said that the membrane is "self-conformable," since it can conform to a surface or space and assume a given configuration, and then be self-retained

in that configuration. In addition, once it is desired to remove the membrane from its stored configuration (e.g., in order to achieve dilation), its deformability is again an advantage.

The membrane 46 of the present invention can be constructed from any one of a number of highly oriented or cross-linked, noncompliant materials, including, without limitation, polymers. Such polymers may preferably undergo an extrusion process in order to achieve their high orientation status, resulting in their noncompliant and substantially inelastic nature. Moreover, such extruded polymers are also very strong and tough, and lubricous as pointed out above. Although other materials within that group are possible, such as polyolefins and their blends which can be highly orientated or cross-linked after radiation treatment and heat forming as found in the art of balloons for angioplasty catheters, in the preferred embodiment, the membrane material is polyethylene terephthalate ("PET"). Other materials include nylon and polyethylene which achieve orientation by pre-stretching whereby the material has high strength and little elongation when a load (stress) is exerted upon it.

The membrane can be constructed from PET tubing which can come in the form of balloon tubing which is pre-stretched and highly orientated for minimal elongation. Other constructions of membranes can use polyolefins and their blends, polyethylene, and nylons which are highly orientated or cross-linked.

Since the membrane 46 is preferably formed on the exterior of the segmented member 36, its natural lubricity provides an important advantage in connection with the ease of insertion of the introducer 30. Advantageously, by forming the membrane on the outer surface of the segmented member, even in its initial configuration, the working space within the central lumen of the device is maximized. However, it will be noted in accordance with the present invention that the membrane 46 may also be formed within the segmented member 36, if desired or necessary.

The Segmented Member

The segmented elongate member 36 provides a central lumen 58 for receiving a medical instrument. The segmented member 36 should be of sufficient rigidity and structural integrity to maintain its overall shape during insertion of the device 30 into a patient's body, and to guide the inserted medical instrument through the central lumen 58 during and after dilation. The segmented member 36 may comprise any number of segments or leaves greater than one. In a preferred embodiment, the segmented member 36 comprises four leaves 38, 40, 42, 44.

The segments or leaves of the segmented member 36 may be provided in various ways. For example, in one embodiment, the segmented member 36 may comprise a plurality of prefabricated slits or perforations along a single piece of metal or plastic which can be split open or separated upon introduction of the larger instrument through the lumen. Further, referring to FIGURES 5A-5E, in a preferred embodiment, the segmented member 36 comprises a plurality of separately formed divisible leaves 38, 40, 42, 44, each having a proximal 60, middle 62 and distal 64 section. In addition, each leaf may be identical to the others. Initially, the leaves 38, 40, 42, 44 are in a tight or close configuration such that the proximal 60, middle 62 and distal 64 sections of each leaf is in close proximity to the respective proximal 60, middle 62 and distal 64 sections of its adjacent leaf or leaves. As illustrated in FIGURE 3C, the leaves 38, 40, 42, 44 may be partially or wholly adhered, bonded or otherwise connected to each other in an initial configuration. Through the use of adhesives, thermal bonding, infrared bonding,

ultrasonic welding or other like methods, the leaves 38, 40, 42, 44 may be affixed to one another yet easily separable or divisible. Moreover, the divisible leaves may be interlocked or connected to each other by an extending piece on one leaf and an accommodating groove on the adjacent leaf. In such a fashion, the leaves may be initially connected to one another.

In a preferred embodiment, each leaf is slightly rounded so that initially, when the proximal 60, middle 62 and distal 64 sections of the plurality of leaves are placed near to each another to form the segmented member 36, the proximal 48 and distal 52 sections of the segmented member 48 are generally cylindrical and profile of the middle section 50 tapers from proximal section to the distal section. In a preferred embodiment, the proximal 60 and distal 64 sections of the leaf 38 each have a constant width, with the width of the distal section 64 being smaller than the width of the proximal section 60. The width of the middle section 62 tapers from that of the proximal section 60 to that of the distal section 64.

As illustrated in FIGURE 5D, in a preferred embodiment, the middle section 62 of the leaf angles away from the distal section 64 of the leaf at an angle α. The angle α, which must be less than 90°, may range from 2° to 20°, and is preferably 3.5°. The angled middle section 62 facilitates both the insertion of the introducer 30 into the patient and helps to guide the medical instrument through the central lumen 58. As illustrated in FIGURE 5E, the proximal section 60 and the distal section 64 can also be tapered or angled at angles θ and β, respectively. Thus, the access device in accordance with the present invention may have any combination of tapered proximal, middle and distal sections, including none.

In a preferred embodiment, due to the tapered profile of the middle section 64, upon introduction of a larger instrument through the central lumen 58, the lumen is gradually expanded as a larger instrument is inserted through the angled middle section 62. The introducer is preferably expanded gradually due to the gentle angle α, thereby reducing pain and discomfort to the patient.

In a preferred embodiment, each leaf or segment has one or more ribs 70 or notches extending longitudinally to further aid in guiding the instrument through the lumen. The ribs 70 also aid in the reduction of surface contact of the instrument against the leaf. As illustrated in FIGURE 7B, the ribs 70 may extend along the sides of the leaves 38, 40, 42, 44, or down the middle of the leaves as in FIGURE 7C, or in other locations, not illustrated.

It is noted that while each leaf alone may be flimsy, the combination of leaves forms a segmented member with sufficient rigidity and structural integrity to be inserted into a patient. The leaves 38, 40, 42, 44 should be thin, and preferably no thicker than .030 inch (0.76mm). The leaves may be made of plastic or metal. In a preferred embodiment, the leaves are metal with a thickness of 0.015 inch (0.38mm). Methods of manufacturing the leaves are discussed in greater detail below.

As illustrated in FIGURE 6, the lumen of the access device can be expanded by introducing into the central lumen an instrument which has a profile larger than the initial working space of the lumen. As the larger instrument is advanced through the lumen 58, the leaves 38, 40, 42, 44 separate or move away from each other in a generally outward direction from the central lumen, thereby enlarging the cross-section of the lumen 58 and the profile of the member 36.

In a preferred embodiment, as the lumen 58 is enlarged, the membrane 46 surrounding the member 36 unfolds or unpleats to accommodate the outward or radial expansion of the member 36. FIGURES 7A-C show a cross-sectional view of the distal end of the member after maximum expansion of the lumen. It should be noted that since the lumen is expanded only so far as necessary to accommodate the instrument, the member may be only partially expanded and does not need to be fully or maximally expanded, as shown in FIGURES 7A-C. Thus, the terms "dilated" and "expanded" may refer to any dilation or expansion, including maximum dilation or expansion, greater than the initial configuration of the access device or central lumen. Method of Construction

The leaves of the segmented member 36 may be metallic or plastic. In a preferred embodiment, each leaf is identical which reduces the cost of manufacturing the device. Further, the leaves are preferably made from stamped metal. Advantageously, the metallic leaves can be made very thin and the cost of manufacturing the metallic leaves is low.

As illustrated in FIGURES 5B-C and FIGURES 7B-C, the ribs 70, notches or other features may be stamped onto the leaf. This in combination with lubricous coatings may reduce the friction of the instrument as it is passed through the introducer. For example, in one embodiment, the inner surface of the leaf, or the surface facing toward the central lumen, is Teflon™ coated to facilitate insertion of the medical instrument. In addition, additional features may be stamped or molded into the leaf which aids in assembly, adhesive application, or insert molding. The leaves can also be made from injection molded plastic and since each individual leaf is identical, the manufacturing costs associated therewith is low.

In the preferred embodiment, the plurality of leaves are arranged in close proximity to each other, or may be touching each other, and attached to the handle to form the segmented member. In another embodiment, the segments or sections of the member are formed by slitting or perforating the elongated member at least partially longitudinally and the member is attached to the handle.

The outer surface of the member is surrounded by the membrane. Excess membrane material may be folded or pleated along the outer surface of the member. Covers or forms are placed onto the folded membrane to closely conform the membrane to the profile of the introducer. These elements keep the membrane in close configuration prior to heat setting. A moderate amount of heat is applied to the access device in order to thermoplastically set the membrane in its stored position. In one preferred embodiment, the PET material which comprises the membrane has a glass transition temperature of 180°F. Thus, the setting temperature used in this method of construction is preferably about 160°F. It will be noted in this regard that sterilization of the system is achieved at about 140°F.

The present method is not limited to that described above. A number of other methods of construction will become apparent to those of ordinary skill. For example, because of the thermoplastic nature of the membrane material, heat forming, heat staking, or heat shrinking can easily be employed in other aspects of the construction method. Although most costly, adhesives or other mechanical fasteners can be utilized. Heat-activated or hot-melt adhesives, UV cured adhesives, or pressure-sensitive adhesive systems can also be used to facilitate attachment of the membrane to the segmented member. Such techniques can also be used for keeping the folded membrane tacked down onto the surface of the segmented member.

Method of Use

While the expandable access device of the present invention can be used in a wide variety of procedures, the introducer 30 is ideally suited for specific procedures, such as tubal sterilization and directed biopsy procedures. In an initial, closed or unexpanded condition, the segmented member 36 and surrounding membrane 46 have a very small profile. The distal tip and section of the segmented member in combination with the membrane provide a streamline entry device which can go through tissue easily. For example, can be placed through the wall of a bodily cavity, for example, the abdomen, in conjunction with a piercing implement, such as a verres needle (shown in phantom) or used in conjunction with vascular access or other applications involving bodily entry.

Once placed through the skin, placement within the peritoneal cavity or other desired location may be observed and confirmed, such as with a small profile endoscope. Grasping the handle 32 of the introducer, the physician can then remove the verres needle or small profile instrument from the central lumen 58 and place a larger instrument, such as a 5, 8 or 10mm device or larger, through the central lumen. More force is required to place the larger instrument through the central lumen initially as the expander dilates the tissue. Clearly, because of the versatility of the surgical access device of the present invention, a number of methods of use are available.

It should be understood that the scope of the present invention is not to be limited by the illustrations or foregoing description thereof, but rather by the appended claims, and certain variations and modifications of this invention will suggest themselves to one of ordinary skill in the art.

WHAT IS CLAIMED IS:

1. An expandable surgical access device comprising:

an elongate member having a lumen for the insertion of a medical instrument, the member comprising a plurality of longitudinal components initially positioned adjacent to one another and forming the lumen, the components being separable to provide expansion of the lumen; and

a membrane interconnecting the components.

2. An expandable surgical access device comprising:

an elongate member having a lumen for the insertion of a medical instrument, the member comprising a plurality of divisible leaves initially positioned adjacent to one another to form the lumen, the components being divisible to provide expansion of the lumen; and

a flexible joint formed between any two adjacent leaves.

3. The access device of Claim 2, wherein the joint comprises a flexible membrane.

4. An expandable surgical access device comprising:

a segmented elongate member providing a lumen for the insertion of a medical instrument, the member having a proximal section and a distal section, the distal section having a smaller profile than the profile of the proximal section; and

a membrane surrounding the segmented elongate member.

5. The surgical access device of Claim 4, wherein the membrane is pleated to provide expansion capability.

6. The surgical access device of Claim 4, wherein the segmented elongate member comprises at least two tapered leaves positioned in an initial tight configuration.

7. The surgical access device of Claim 4, wherein the membrane is a thin, strong material which is thermally, mechanically, and/or chemically settable so that prior to expansion of the access device, the membrane retains its storage position.

8. The surgical access device of Claim 7, wherein the membrane is polyethylene terephthalate.

9. A radially expandable surgical access device having an outer surface defining at any particular location along its longitudinal axis, a cross-sectional profile, the device comprising:

a handle;

a segmented member providing a lumen for the insertion of a medical instrument or visualization device, the member having a cylindrical proximal section connected to the handle in an initial tight configuration, a tapered middle section, and a cylindrical distal section, the profile of the distal section being smaller than the profile of the proximal section; and

a thin, polymer membrane surrounding the leaves and which, prior to expansion, so closely conforms to the outer surface of the surgical access device that it only negligibly increases the size of the profile of the surgical access device.

10. The radially expandable surgical access device of Claim 9, wherein the membrane is thermoplastically set in position along the outer surface of the access device.

11. A method of expanding the effective diameter of a puncture site, comprising the steps of:

introducing into a patient an expandable surgical access device comprising a segmented elongate member having a lumen extending axially therethrough, the member in an initial close configuration surrounded by a membrane; and

inserting through the lumen of the access device a medical instrument or visualization device with a diameter larger than the initial diameter of the lumen such that the medical instrument separates the segments of the segmented elongate member and unpleats the membrane.

12. A method of manufacturing a radially expandable surgical access device, comprising the steps of:

providing at least two thin, tapered leaves made from stamped metal;

positioning the leaves in close proximity defining a lumen with a proximal end and a distal end, the diameter at the proximal end larger than the diameter at the distal end;

surrounding the leaves with a thin, lubricous polymer membrane;

pleating the membrane; and

pressing the pleated membrane onto the outer surface of the leaves.

13. The method of manufacturing a radially expandable surgical access device as in Claim 12, further comprising the step of temporarily affixing the leaves to each other in such a way that so that the leaves are easily separable upon the introduction of an instrument through the lumen.

14. The method of manufacturing a radially expandable surgical access device as in Claim 12, wherein the leaves are temporarily affixed to each other by thermal bonding.

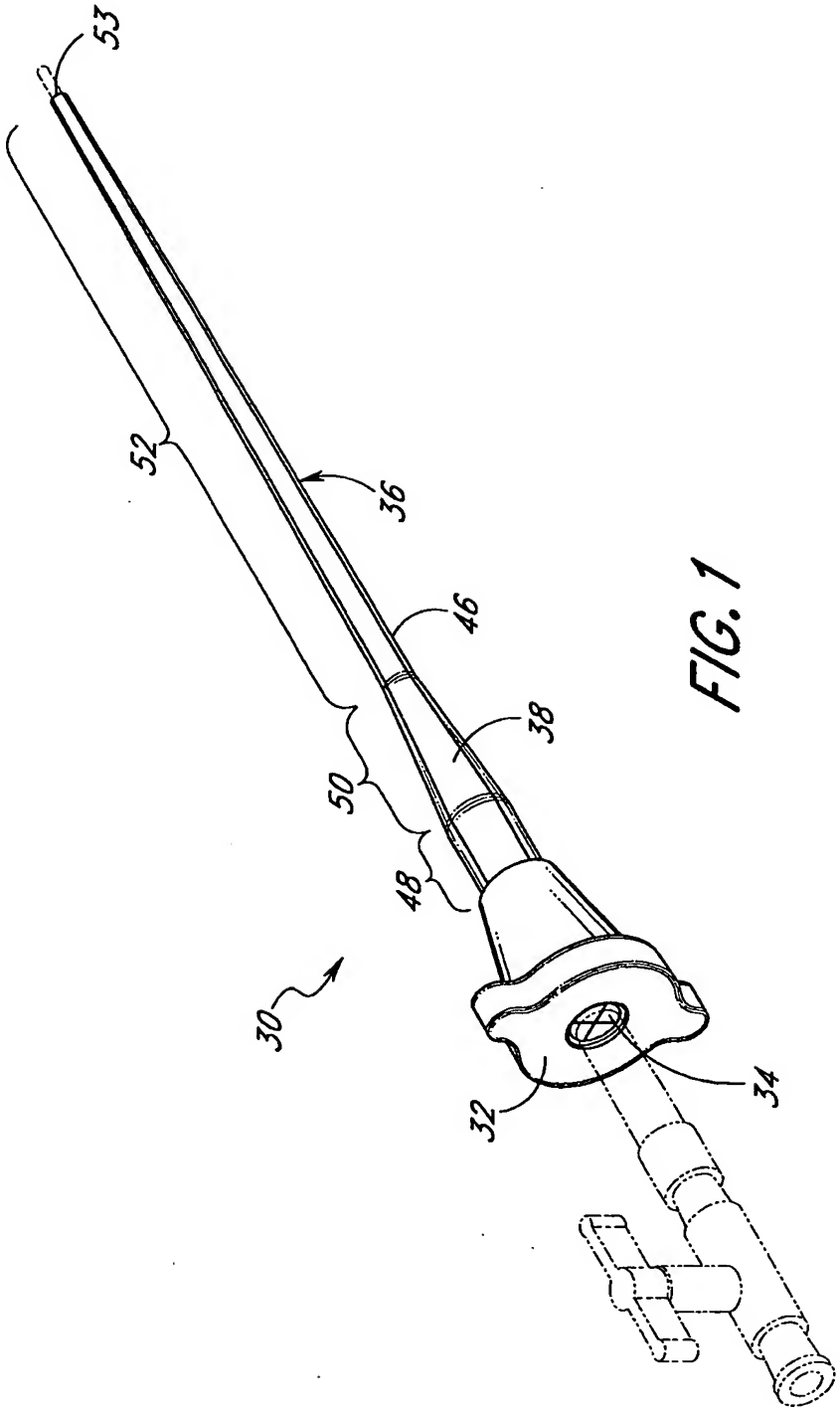

FIG. 1

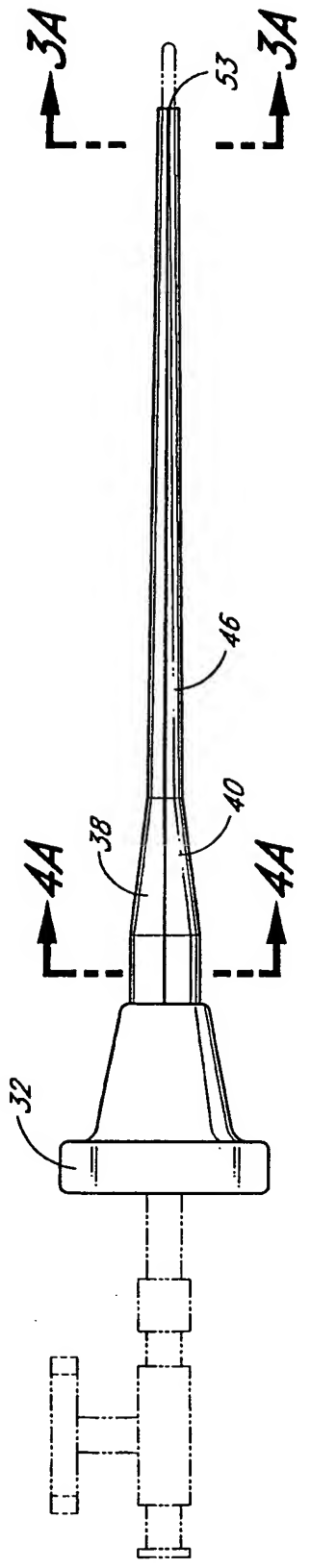

FIG.2

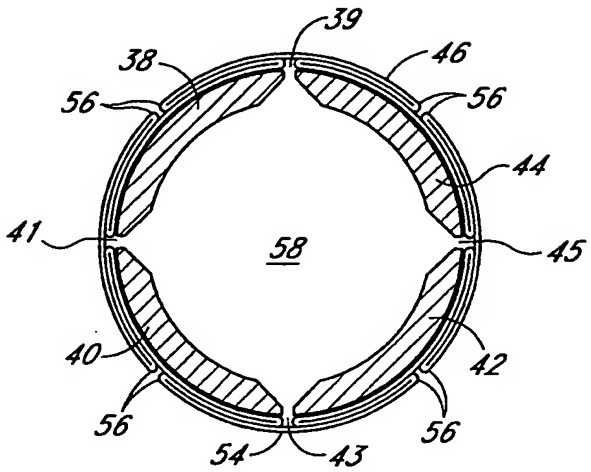

FIG. 3A

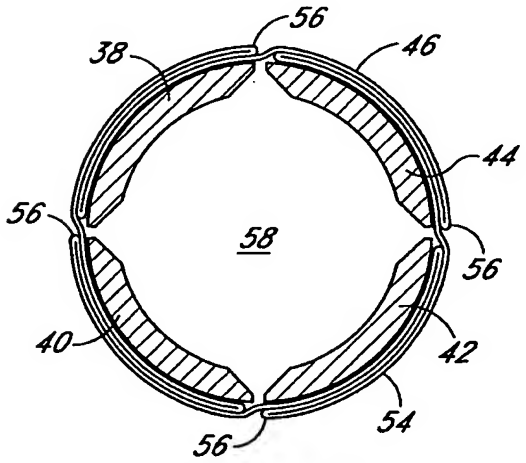

FIG. 3B

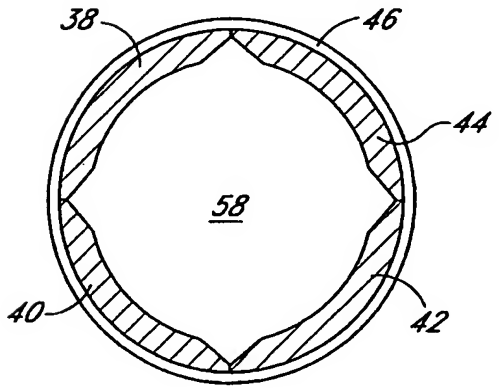

FIG. 3C

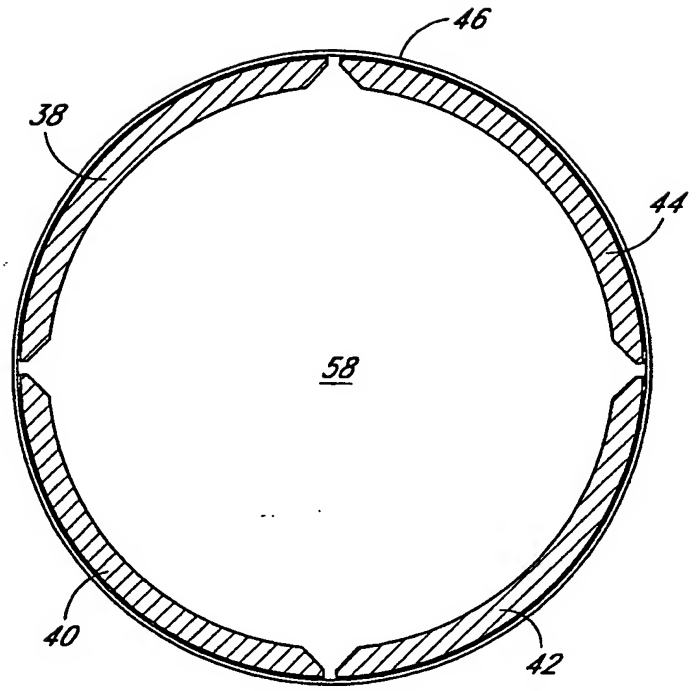

FIG. 4A

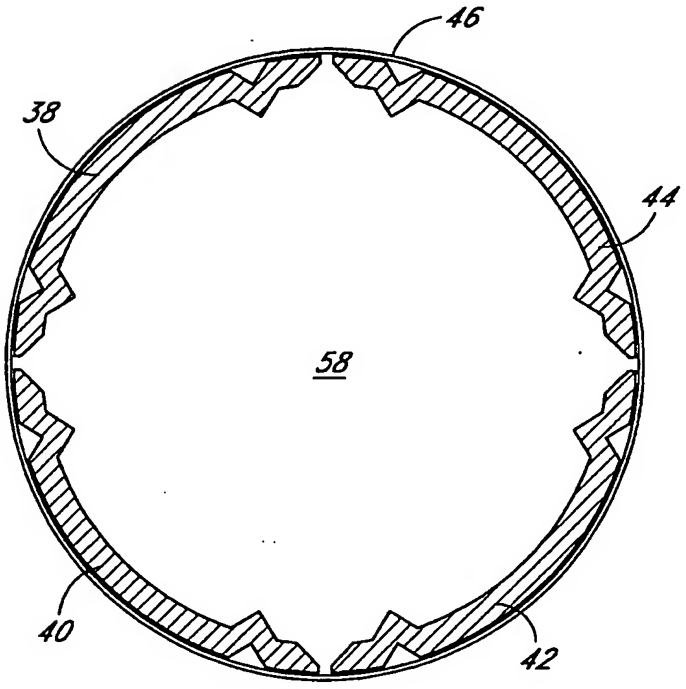

FIG. 4B

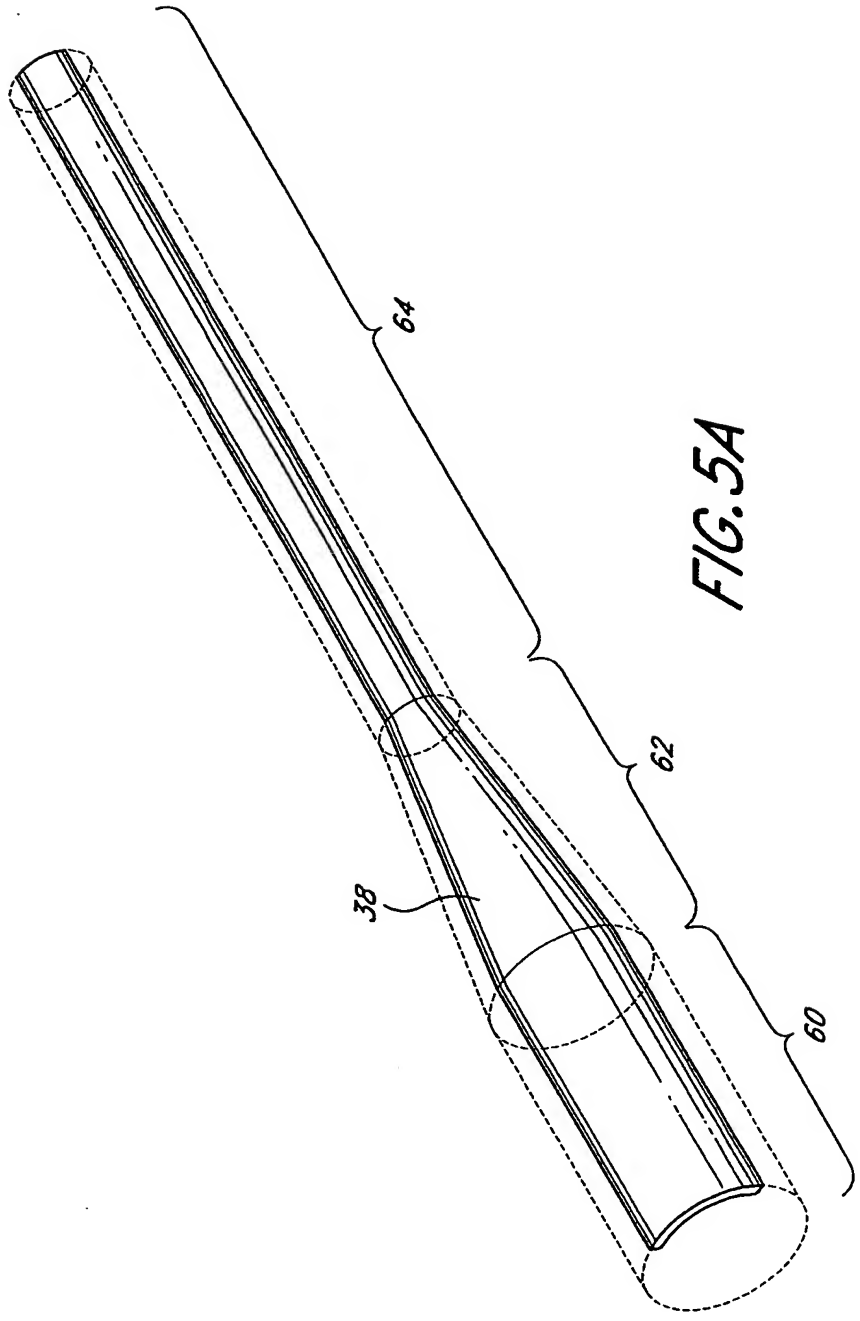

FIG. 5A

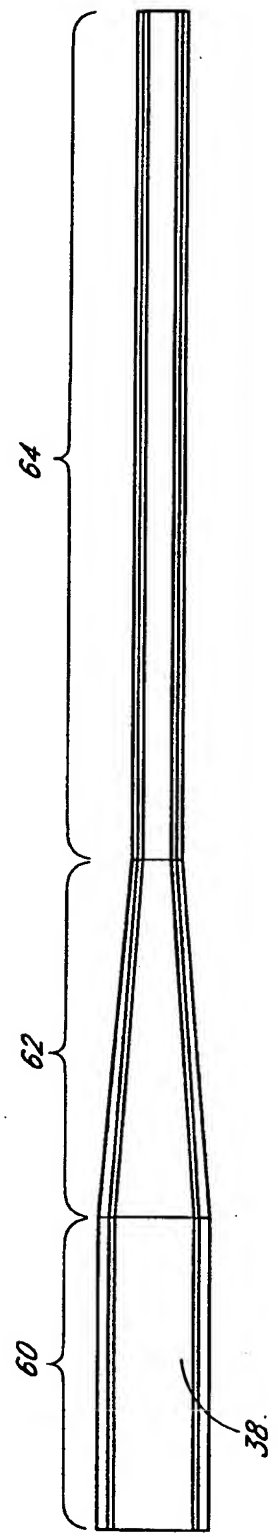

FIG. 5B

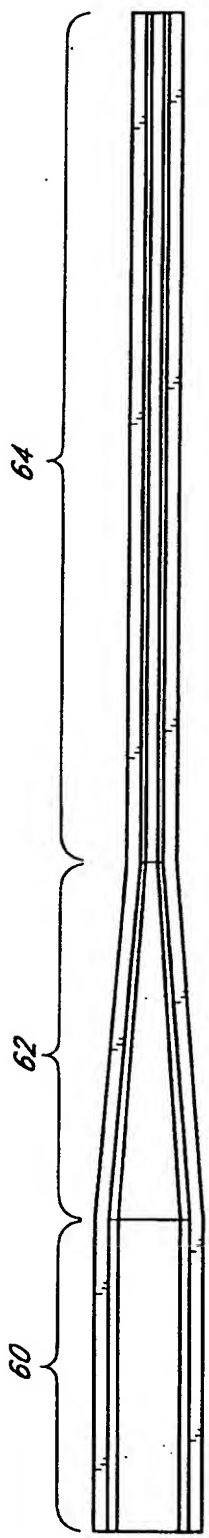

FIG. 5C

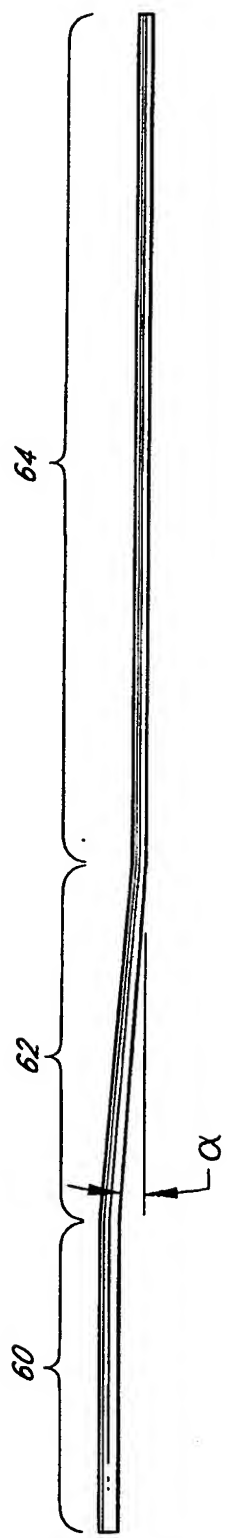

FIG. 5D

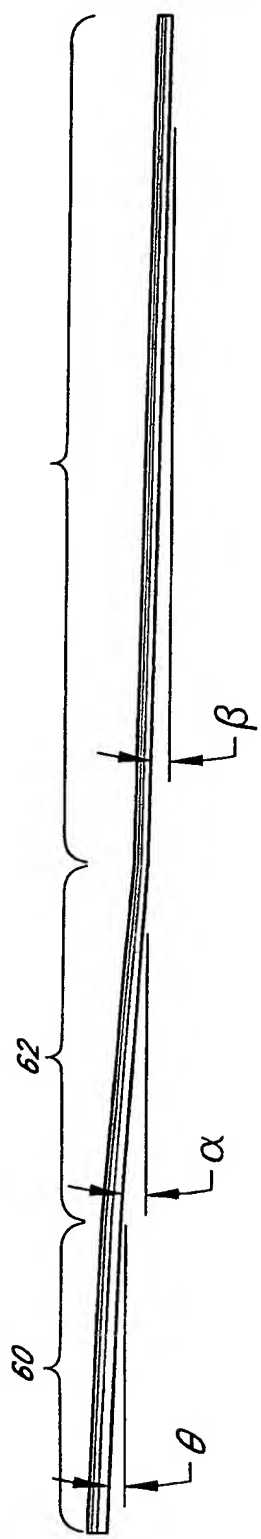

FIG. 5E

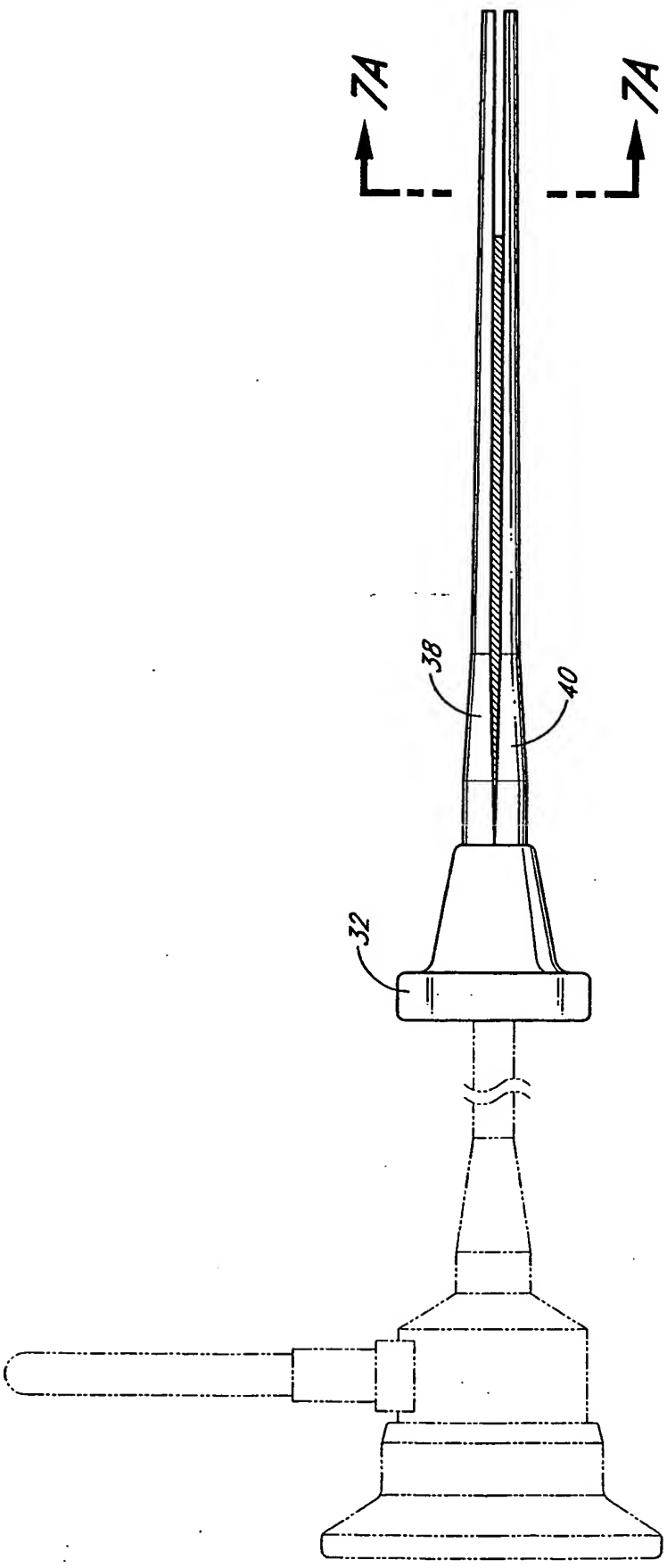

FIG. 6

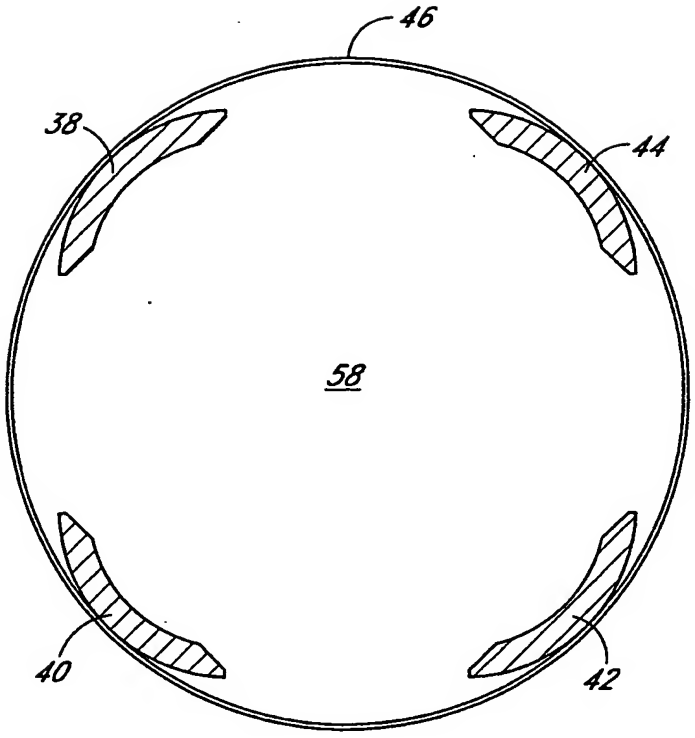

FIG. 7A

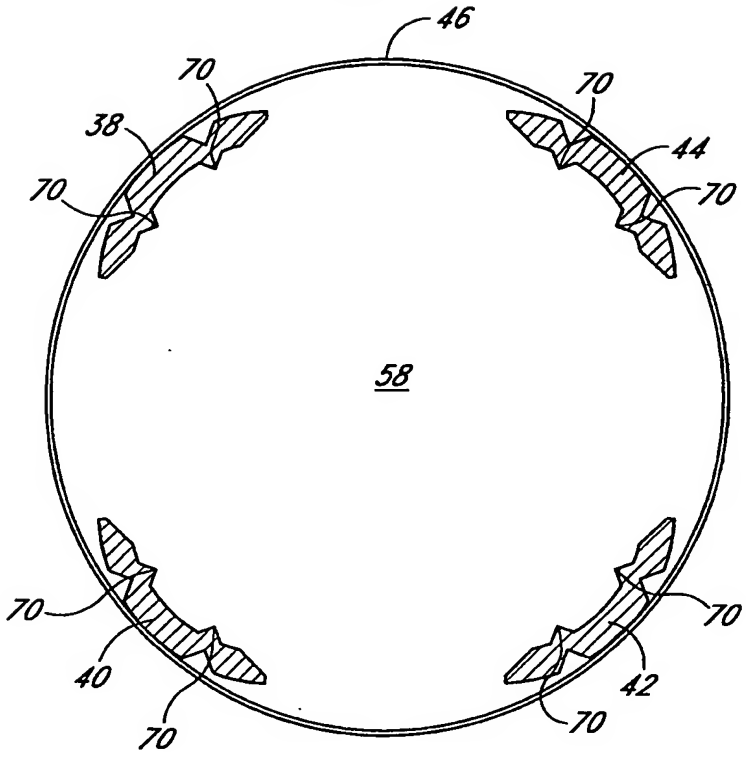

FIG. 7B

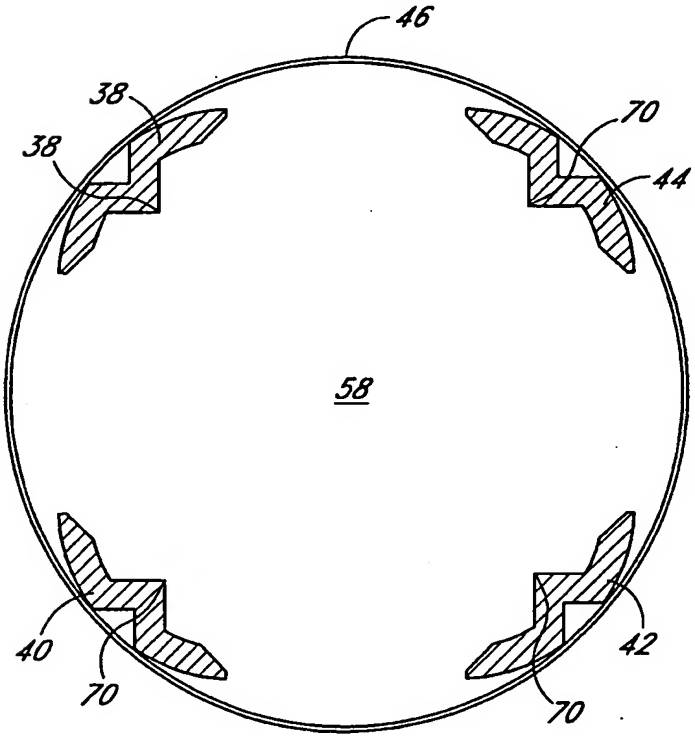

FIG. 7C